PHARMACARE NEWSLETTER

Use of Antidepressants in Patients Under Age 18

As you may know, Health Canada has recently issued a Health Advisory to Canadians indicating patients under the age of 18 should consult their physicians if they are being treated with one of the newer antidepressants, Selective Serotonin Re-Uptake Inhibitors (SSRIs) or Serotonin Noradrenaline Re-Uptake Inhibitors (SNRIs), to confirm that the benefits of the drug still outweigh its potential risks in light of recent safety concerns. Health Canada has indicated that SSRI/SNRI drugs have not been approved for use in patients under 18 years. A copy of the Health Canada advisory which contains the list of antidepressant drugs included in the advisory is enclosed.

As a result of international reports that some of the newer antidepressants may be associated with an increased risk of suicide-related events in patients under 18 years of age, Health Canada has requested the manufacturers of these newer antidepressants to provide a thorough review of the worldwide safety data.

The Medicines and Healthcare Products Regulatory Agency (MHRA), the Executive Agency of the United Kingdom Department of Health, responsible for protecting and promoting public health and patient safety, for example, has developed a number of documents on the use of SSRIs in children and adolescents with major depressive disorder www.mhra.gov.uk/news/2003.htm#ssri.

Dr. E. Jane Garland, Clinical Professor - Psychiatry, Clinical Head - Mood and Anxiety Disorders Clinic, British Columbia's Children's Hospital, has provided the most current summary of the 15 clinical trials that have been published to date on SSRI efficacy in children under 18 years of age, in the most recent edition of the Canadian Medical Association Journal – CMAJ February 17, 2004; 170 (4): 489-491 www.cmaj.ca/cgi/content/full/170/4/489.

In her article, Dr. Garland indicates that after a period of careful observation and a trial of non-pharmacological therapies, children with persistent and severe depression or co-morbid anxiety disorders may need to be treated with medications. The article reinforces that psychiatric adverse effects of SSRIs overlap with manifestations of depression which may require a decision to decrease the dose in children experiencing adverse effects. Abrupt withdrawal of these drugs may result in discontinuation symptoms which may manifest in emotional and behavioural discontinuation effects. No SSRI should be stopped abruptly and gradual decrease in dose may be required.

It is important that families are informed that psychiatric or behavioural adverse effects may occur with these drugs. Please note that community mental health services for children and youth are available through the child and youth mental health team at your local Ministry of Children and Family Development Office.

It is also important that patients, parents, physicians, pharmacists and other health professionals are aware that patients should not abruptly stop taking their medications but should consult their physician for advice on treatment.

Questions pertaining to the Health Canada Advisory can be directed to the Therapeutic Products Directorate by calling the Health Canada Public Inquiries Line at (613) 957-2991.

Text of the Advisory issued by Health Canada on February 3, 2004

2004-02
February 3, 2004
For immediate release

Advisory

Correction

Health Canada advises Canadians under the age of 18 to consult physicians if they are being treated with newer anti-depressants

OTTAWA - Health Canada is advising Canadians that patients under 18 who are currently being treated with a newer anti-depressant -- Selective Serotonin Re-uptake Inhibitors (SSRIs) or Serotonin Noradrenaline Re-uptake Inhibitors (SNRIs) -- should consult their treating physician to confirm that the benefits of the drug still outweigh its potential risks in light of recent safety concerns.

Health Canada recently requested that the manufacturers of the newer anti-depressants provide a thorough review of the worldwide safety data for their drug when used in children under 18 years of age. This request was made as a result of international reports that some of these drugs may be associated with an increased risk of suicide-related events in patients under 18 years of age.

It is important to note that Health Canada has not approved these drugs for use in patients under 18 years. The prescribing of drugs is a physician's responsibility. Although SSRI/SNRIs are not approved for use with children, doctors rely on their knowledge of patients to determine whether to prescribe them at their discretion in a practice called off-label use.

Health Canada does not advise that paediatric patients discontinue use of a newer anti-depressant without first consulting their treating physician, as treatment with these drugs should not be abruptly stopped due to the risk of discontinuation symptoms. This advisory does not apply to the approved uses of these drugs in adults.

This advisory applies to the following antidepressants:

- Citalopram (Celexa®)
- Fluoxetine (Prozac®)
- Fluvoxamine (Luvox®)
- Mirtazapine (Remeron®)
- Paroxetine (Paxil®)
- Sertraline (Zoloft®)
- Venlaflaxine (Effexor®)

Media Inquiries:
Jirina Vlk
Health Canada
(613) 957-2988

Public Inquiries:
(613) 957-2991